

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:	RECEIVED MAR 06 2009 see form PCT/ISA/220 BROMBERG & SUNSTEIN LLP
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**
(PCT Rule 43bis.1)

Applicant's or agent's file reference see form PCT/ISA/220	FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US2008/066994	International filing date (day/month/year) 13.06.2008	Priority date (day/month/year) 13.06.2007
International Patent Classification (IPC) or both national classification and IPC INV. A61B17/17 ADD. A61B19/00 A61B17/00 A61B17/15		
Applicant CONFORMIS, INC.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application


2. FURTHER ACTION

If a demand for International preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Fernández Arillo, J
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/066994

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☒ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material:

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material:

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing:

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. 20-38, 54-59, 65

because:

- ☒ the said international application, or the said claims Nos. 20-38, 65 relate to the following subject matter which does not require an international search (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*Indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):
- ☒ no international search report has been established for the whole application or for said claims Nos. 20-38, 54-59, 65
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/066994

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-19, 39-53, 60-64

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>18</u>
	No: Claims	<u>1-17, 19, 39-53, 60-64</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-19, 39-53, 60-64</u>
Industrial applicability (IA)	Yes: Claims	<u>1-19, 39-53, 60-64</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2008/066994

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)
and /or
2. Non-written disclosures (Rules 43*bis*.1 and 70.9)
see form 210

1.- Reference is made to the following documents:

D1: EP0337901 A 19891018

D2: WO2004049981 A 20040617

2.- Re Item III.

The subject-matter of **claims 20-38 and 65** relates to a method for treatment of the human body by surgery, since, in view of the description, it is clear that the surgical instrument is guided during a surgical operation (see also claim 22, which further includes the step of cutting the tissue). Therefore, pursuant to Rule 39.1(iv) PCT, the subject-matter of said claims has not been searched.

3.- Re Item IV

This Authority considers that there are 2 groups of potential inventions covered by the claims indicated as follows:

I: **Claims 1-19, 39-53, 60-64** directed to a guide having a surface conforming to a patient's tissue for solving the problem of improving the attachment of the guide to said tissue.

II: **Claims 54-59** directed to a surgical tool comprising one insert and a template including a guide.

The only **common technical feature** linking together both groups of potential inventions is **the presence of a surgical guide**, which is, obviously, a well-known feature and **cannot** be considered to be **special** in the sense of Rule 13.2 PCT. The two groups of potential inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, since they are not linked by common or corresponding **special** technical features (Rule 13.2 PCT). Thus, the present application lacks unity "a priori", that is, before considering the claims in relation with any prior art (see Guidelines PCT/GL/ISPE/1,

10.03).

4.- Re Item V.

4.1 Clarity

The subject-matter of **claim 1** is not clear in the sense of Article 6 PCT, since the "contact surface" of the third line and the "stop" of the last paragraph are both defined with respect to the patient, who is not part of the claimed guide. It is also not clear, how the stop is based on patient specific information. Furthermore it is to be noted that this definition, as far as it could be understood, does not restrict the scope the claim, since there can be found for any guide of the prior art a patient to whom said guide is specifically adapted.

The same objection applies to **claims 6, 7 to 10, 12, 39, 40, 41, 44, 45, 48, 49, 52, 53, 60, 62, 63 and 64**.

4.2 Novelty

4.2.1 The subject-matter of **claim 1** is not new in the sense of **Article 33(2) PCT**, since D1 (see D1, fig. 6) discloses (the references in parentheses applying to D1):

A surgical cutting guide (7) for guiding a surgical instrument along a cutting path located on a biological tissue, the cutting guide comprising:
a contact surface that conforms (see fig. 6) to a surface associated with the tissue (see remark 4.1 above);
at least one guide (upper horizontal surface of 7) for restricting movement of a surgical instrument in a first direction and for allowing the movement of the surgical instrument in a second direction along a cutting path across the surface of the tissue; and
a stop (8, see also col. 4 l. 7-11) for restricting movement of the surgical instrument in the second direction along the cutting path (**claim 1**).

4.2.2 The subject-matter of **claims 2-17, 19, 39-53, 60-64** is not new in the sense of

Article 33(2) PCT, since D1 (see D1, fig. 6) further discloses the following features (the references in parentheses applying to D1):

the abutments of **claims 2 and 3** (see D1, fig. 6),
the contact of **claim 4** (see D1, fig. 6),
the tissue of **claim 6**,
the features of **claims 5, 7 to 10, 12, 39, 40, 44, 52, 53, 60, 62, 63 and 64** (see clarity objection 4.1 above),
the cutting plane of **claim 11**,
the stops (8) of **claims 13, 14, 15, 41, 45, 48, 49 and 61**,
the features of **claim 16** (note that the surgical instrument is not part of the claimed guide),
the use (knee) of **claims 17, 42, 43, 46 and 47**,
the perpendicularity of **claim 19**, and
the attachments of **claims 50 and 51**.

4.3 Inventive step

The subject-matter of **claim 18** does not involve an inventive step in the sense of **Article 33(3) PCT**, since D2 (see D2 para. 255, 268 and 269) discloses a guide with a contact surface having a plurality of concavities and convexities for solving the same problem as the present application, namely, to better conform to the bone surface. The combination of D1 and D2 to come to a guide according to **claim 18** would therefore be obvious to the skilled person.

4.4 Further remarks

3.4.1 Claims 1, 39, 40, 41, 45, 48, 49, 52, 54, 60 and 63 have been drafted as separate independent claims. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

3.4.2 It is to be noted that the guide of D2 is manufactured (see D2 para. 255, 268 and 269) in the same way as the one of the present application, namely, based on patient's specific information previously obtained, thereby solving the problem of providing a customized guide.